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Ziping Liu

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8965

22466

7590

06/25/2010

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GLOBAL INTELLECTUAL PROPERTY
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EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

06/25/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Status of Claims

Claims 3, 4, 10 and 17 are currently pending in the instant application. Claims 1-2, 5-9 and 11-16 have been cancelled.

Receipt is acknowledged of amendment / response filed on May 07, 2010 and that has been entered.

Response to Arguments

Previous Claim Rejections - 35 U.S.C. § 102

Applicant's amendments and arguments [to withdrawal of the rejection of claims 3-4 and 10 under 35 U.S.C. § 102(b)] have been fully considered and found persuasive with respect to the above rejection and the rejection is hereby withdrawn. However, upon further consideration, the following new ground of rejection is made and therefore, Applicants arguments are rendered moot in view of the present Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

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invention. The claims contain the subject matter of a newly introduced **proviso** such as, ”

and

the compound is not:

N-(2-*tert*-Butyl-1-(cyclohexylmethyl)-1*H*-benzimidazol-5-yl)-*N,N,N*,*N*-trimethylsulfamide;

N-(2-*tert*-Butyl-1-(cyclohexylmethyl)-1*H*-benzimidazol-5-yl)-*N,N*-diethyl-*N*-methylsulfamide;

N-(1-(cyclohexylmethyl)-2-(1,1-dimethylpropyl)-1*H*-benzimidazol-5-yl)-*N,N*-dimethylsulfamide;

N-(2-*tert*-Butyl-1-(tetrahydro-2*H*-pyran-4-ylmethyl)-1*H*-benzimidazol-5-yl)-*N*-methylbutane-1-sulfonamide;

N-(2-*tert*-Butyl-1-(tetrahydro-2*H*-pyran-4-ylmethyl)-1*H*-benzimidazol-5-yl)-*N*-methyl-2-pyrrolidin-1-ylethanesulfonamide;

N-(2-*tert*-Butyl-1-(tetrahydro-2*H*-pyran-4-ylmethyl)-1*H*-benzimidazol-5-yl)-*N*-methyl-2-morpholin-4-ylethanesulfonamide;

N-(2-*tert*-Butyl-1-(tetrahydro-2*H*-pyran-4-ylmethyl)-1*H*-benzimidazol-5-yl)-*N*-methyl-2-piperidin-1-ylethanesulfonamide;

N-(2-*tert*-Butyl-1-(tetrahydro-2*H*-pyran-4-ylmethyl)-1*H*-benzimidazol-5-yl)-2-methoxy-*N*-methylethanesulfonamide;

N-(2-*tert*-Butyl-1-(tetrahydro-2*H*-pyran-4-ylmethyl)-1*H*-benzimidazol-5-yl)-2-[(2-hydroxyethylamino)-*N*-methylethanesulfonamide];

2-(2-Aminoethoxy)-N-[2-tert-butyl-1-(tetrahydro-2H-pyran-4-ylmethyl)-1H-benzimidazol-5-yl]-N-methylethanesulfonamide;



N-[2-tert-Butyl-1-(tetrahydro-2H-pyran-4-ylmethyl)-1H-benzimidazol-5-yl]-N-methylethanesulfonamide;

N-[2-tert-Butyl-1-[(4,4-difluorocyclohexyl)methyl]-1H-benzimidazol-5-yl]-N-methylbutane-1-sulfonamide;

N-[2-tert-Butyl-1-[(4,4-difluorocyclohexyl)methyl]-1H-benzimidazol-5-yl]-N-methyl-2-piperidin-1-ylethanesulfonamide and/or pharmaceutically acceptable salts thereof.

” [claim 3 (Currently amended), pages 3-4] to overcome the prior art rejection. This proviso subject matter is considered **new matter** since the specification and the originally filed claims were excluded this proviso from the compounds as can be seen by original claims 1-5 and 8-16 and in the specification on pages 1-44. The amendment changes the scope of the claims to include a negative limitation and proviso compounds that were not previously included in the invention. This rejection can be overcome by deleting the new matter from the instant claims and also amend the claims within the context and scope of the claims (limiting with specific type of compounds that actually contemplated in the specification) in order to overcome the rejection.

Previous Claim Rejections - Double Patenting

Applicant's response and arguments [to withdrawal of the rejection of claims 3-4 and 10 under the judicially created doctrine of obviousness-type double patenting over claims 1-2 of US 7,550,495 have been fully considered and found unpersuasive and the rejection has been maintained for the reasons given in the last Office action mailed on 01/07/2010. Applicant's arguments have been fully considered but are not deemed persuasive because Applicants'

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arguments unsupported by objective and competent factual evidence are entitled to little weight.

In re Greenfield 197 USPQ 227. *In re Lindner* 173 USPQ 356. Applicant alleges,
“

Claims 1 and 2 of the '495 patent do not teach or suggest Formula 1, the radical groups R¹, R², R³ and R⁴, or definitions of these radical groups. Because claims 1 and 2 of the '495 patent do not teach or suggest all the limitations of claims 3, 4 and 10 of the present invention,
”

(Remarks, page 8). The Examiner respectfully disagrees, because these assessments are speculation on Applicant's behalf, since '495 patent teach the compound and composition [such as, corresponding R¹ is C₃₋₁₀cycloalkyl-C₁₋₄alkyl (substituted by halogen) and R² is optionally substituted C₁₋₆alkyl etc], which are within the boundaries of the instantly claimed compounds and compositions). The instantly claimed compounds are so closely related structurally to the homologous and /or analogous compounds of the references as to be structurally obvious, therefore, in the absence of any unobviousness or unexpected properties. Therefore, in the absence of objective evidence showing an unexpected result (supported by affidavit and / or declaration), the obviousness-type double patenting rejection is deemed to be proper and hence, this rejection must be maintained.

Claims 3-4, and 10, are also rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 1-4, and 10 of co-pending Application No. 10/572,825, over claims 1-4, and 10 of co-pending Application No. 10/572,826, over claims 1-8, and 13 of co-pending Application No. 12/466,415, and also over claims 1-6 and 12 of co-pending Application No. 11/575,691.

Applicant's response and arguments, "this is a provisional double patenting rejection, Applicants will further respond as necessary once the claims are otherwise found allowable,"⁸ Remarks, page 8] have been fully considered and found unpersuasive with respect to the above rejection of claims 3-4 and 10 under the judicially created doctrine of obviousness-type double patenting. Since the Applicant did not traverse the merit of obviousness-type double patenting rejection, and the instant claims are not yet under condition for allowance and hence, the obviousness-type double patenting rejection is deemed to be proper and, therefore, this rejection must be maintained.

A timely filed Terminal Disclaimer may be used to overcome the above rejection.

Therefore, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 7:30 AM - 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (571) 273-8300. When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/
Primary Examiner
Art Unit 1626
Technology Center 1600

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